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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,155	01/03/2007	Takaji Wakita	1254-0299PUS1	6809

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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
07/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/558,155	WAKITA ET AL.	
	Examiner	Art Unit	
	FEREYDOUN G. SAJJADI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21 are pending in the application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

1. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13 and 21, drawn to a replicon RNA, comprising a nucleotide sequence containing at least the 5' untranslated region, the nucleotide sequence encoding NS3 protein, NS4A protein, NS4B protein, NS5A protein and NS5B protein and the 3' untranslated region on the genomic RNA of hepatitis C virus (HCV) of genotype 2a, and a replicon-replicating cell comprising said replicon RNA.

Group II, claim(s) 14 and 15, drawn to a method of producing an HCV replicon RNA and a method of producing an HCV viral protein from a replicon-replicating cell, comprising extracting replicon RNA or obtaining viral protein from said cell.

Group III, claim(s) 16, drawn to a method of screening fro a substance promoting or suppressing replication of HCV, comprising culturing a replicon-replicating cell in the presence of a test substance and detecting the replication of a replicon RNA.

Group IV, claim(s) 17-20, drawn to a method of increasing the replication efficiency of an HCV replicon RNA, comprising introducing a replicated replicon RNA into a non-parental cell to produce a new replicon-replicating cell; and a method of producing an HCV replicon RNA having increased replication efficiency, comprising detecting a nucleotide or an amino acid mutation associated with an increased replication efficiency, and introducing said mutation into a replicon RNA.

Please note that PCT Rule 13.2, no longer specifies the combinations of categories of invention which are considered to have unity of invention. The categories of invention in former PCT Rule 13.2 have been replaced with a statement describing the method for determining whether the requirement of unity of invention is satisfied. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

2. Group I claims 1-13 and 21 encompass a plurality of distinct inventions exemplified by structurally distinct nucleic acid sequences. These are exemplified by SEQ ID NOS: 1, 2, 3, 5, 9, 10, 11 and 12. Because the nucleic acid sequences have distinct structural sequences, not commonly shared, they lack unity of invention. Applicant is required to choose a single, specific SEQ ID NO for the replicon RNA (either SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3 or SEQ ID NO: 5 should the inventions of Groups I be elected for examination. Applicants are further required to choose either SEQ ID NO: 9 or SEQ ID NO: 10; and either SEQ ID NO: 11 or SEQ ID NO: 12, corresponding the 5' and 3' untranslated regions, respectively. The specific SEQ ID NOS for the untranslated regions should further be commensurate in scope with the elected SEQ ID NOS: 1, 2, 3 or 5. This is not a species restriction requirement.

Applicants should note that while MPEP 803.04 allows for the examination of up to ten sequences in a single examination without restriction, the waiver for up to 10 nucleotide sequences is permissive and not a requirement. The waiver went into effect in 1996, well before the exponential growth of the nucleic acid and protein databases. Since the addition of these guidelines to the MPEP the biological sequence databases required to be searched for the examination of any biological sequence have grown tremendously (e.g. a 54-fold increase in the number of nucleic acid sequences in the GenBank data base and a 91-fold increase in the number of nucleotides between 1996 and February 2006), and thus the Technology Center no longer routinely examines and searches more than one independent biological sequence for any single application (a pre-OG notice <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/sequence02212007.pdf). The

present restriction requirement conforms with this policy as it has required that the application be restricted to one nucleotide polypeptide sequence.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature, which is shared by Groups IV is a replicon RNA of HCV genotype 2a.

Groups I-IV do not share a special technical feature over the art because the inventions lack an inventive step under PCT Article 33(3) as being obvious over WO 00/75338 (PCT Application Publication; published 14 December 2000; of record). WO 00/75338 describes nucleic acid sequences encoding HCV gentoype 2a, and polypeptides encoded by all or part of the sequence for the development of vaccines and diagnostics for HCV and screening for HCV antiviral agents (Abstract).

The claims in Groups I-IV are drawn to a distinct product, and methods, requiring non-coextensive search and examination. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A specifically named marker gene or a specifically named reporter gene (claim 2), as recited on pp. 16-17 of the specification.

A specifically named liver-derived, uterine cervix-derived or fetal kidney-derived human cell, and either Huh7, HepG2, IMY-N9, HeLa or 293 cell, commensurate with the scope of human cell, as recited in claims 8 and 9.

A specific replicon RNA mutation corresponding to SEQ ID NO: 1, as recited in claim 21, (a) to (u).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1, 3, 5, 6, 14-17, 19-21 and claims dependent therefrom correspond to all the species listed above.

The following claim(s) are generic: 1-21.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical features (marker gene, reporter gene, liver-derived, uterine cervix-derived, fetal kidney-derived human cell, Huh7, HepG2, IMY-N9, HeLa, 293 cell and various point mutations of SEQ ID NO: 1) linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species is structurally and likely functionally distinct, and does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is

withdrawn by the examiner before the patent issues. See MPEP § 804.01.Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/

Fereydoun G. Sajjadi, Ph.D.
Examiner, Art Unit 1633